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FDA REGULATION UNDER FOOD ADDITIVE LAW

The Food and Drug Administration published in the Federal Register of November 20 a regulation listing substances that are generally recognized as safe within the meaning of the 1958 Food Additives Amendment to the Food and Drug Act.

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart B—Exemption of Certain Food Additives From the Requirement of Tolerances

SUBSTANCES THAT ARE GENERALLY RECOGNIZED AS SAFE

Pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug and Cosmetic Act (secs. 409, 701, 72 Stat. 1785, 52 Stat. 1055, as amended 72 Stat. 948; 21 U.S.C. 348, 371), and delegated to the Commissioner of Food and Drugs by the Secretary (23 F.R. 9500), and after having considered all comments on the proposed order published in the FEDERAL REGISTER of December 9, 1958 (23 F.R. 9511), containing a list of substances regarded as generally recognized as safe within the meaning of section 409 of the act, the Commissioner has concluded that the substances in that list with the exception of carbon black, charcoal, oleic acid, linoleic acid, titanium dioxide, and ultramarine blue, are generally recognized as safe. *Therefore, it is ordered*, That the food additive regulations (21 CFR Part 121 (24 F.R. 1095)) be amended by adding thereto, under Subpart B, the following new section:

§ 121.101 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by

way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. The lists in paragraph (d) of this section include additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are as follows:

CHEMICAL PRESERVATIVES

Ascorbic acid.
Ascorbyl palmitate.
Calcium ascorbate.
Calcium propionate.
Erythorbic acid.
Potassium sorbate.
Propionic acid.
Sodium ascorbate.
Sodium propionate.
Sodium sorbate.
Sorbic acid.
Tocopherols.

BUFFERS AND NEUTRALIZING AGENTS

Acetic acid.
Aluminum ammonium sulfate.
Aluminum sodium sulfate.
Aluminum potassium sulfate.
Ammonium bicarbonate.
Ammonium carbonate.
Ammonium hydroxide.
Ammonium phosphate (mono- and di-basic-).
Calcium carbonate.
Calcium chloride.
Calcium citrate.
Calcium gluconate.
Calcium hydroxide.
Calcium lactate.
Calcium oxide.
Calcium phosphate.
Citric acid.
Lactic acid.
Magnesium carbonate.
Magnesium oxide.
Potassium acid tartrate.
Potassium bicarbonate.
Potassium carbonate.
Potassium citrate.
Potassium hydroxide.
Sodium acetate.
Sodium acid pyrophosphate.
Sodium aluminum phosphate.
Sodium bicarbonate.
Sodium carbonate.
Sodium citrate.
Sodium hydroxide.
Sodium phosphate (mono-, di-, tri-).
Sodium potassium tartrate.
Sodium sesquicarbonate.
Sulfuric acid.
Tartaric acid.

EMULSIFYING AGENTS

Diacyl tartaric acid esters of mono- and diglycerides from the glycerolysis of edible fats or oils.

Mono- and diglycerides from the glycerolysis of edible fats or oils.

Monosodium phosphate derivatives of mono- and diglycerides from the glycerolysis of edible fats or oils.

Propylene glycol.

MISCELLANEOUS

Acetic acid.
Aluminum sodium sulfate.
Aluminum sulfate.
Butane.
Calcium phosphate, tribasic.
Caramel.
Carbon dioxide.
Carnauba wax.
Citric acid.
Glycerin.
Glycerol monostearate.
Helium.
Magnesium carbonate.
Magnesium hydroxide.
Monoammonium glutamate.
Nitrogen.
Papain.
Phosphoric acid.
Propane.
Propylene glycol.
Triacetin (glyceryl triacetate).
Tricalcium phosphate.
Sodium carbonate.
Sodium phosphate.
Sodium tripolyphosphate.

NONNUTRITIVE SWEETENERS

Calcium cyclohexyl sulfamate.
Calcium saccharin.
Saccharin.
Sodium cyclohexyl sulfamate.
Sodium saccharin.

NUTRIENTS

Ascorbic acid.
Calcium carbonate.
Calcium oxide.
Calcium pantothenate.
Calcium phosphate (mono-, di-, tribasic).
Calcium sulfate.
Carotene.
Ferric phosphate.
Ferric pyrophosphate.
Ferric sodium pyrophosphate.
Ferrous sulfate.
Iron, reduced.
L-Lysine monohydrochloride.
Niacin.
Niacinamide.
D-Pantothenyl alcohol.
Potassium chloride.
Pyridoxine hydrochloride.
Riboflavin.
Riboflavin-5-phosphate.
Sodium pantothenate.
Sodium phosphate (mono-, di-, tribasic).
Thiamine hydrochloride.
Thiamine mononitrate.
α-Tocopherol acetate.
Vitamin A.
Vitamin A acetate.
Vitamin A palmitate.
Vitamin B₁.
Vitamin B₂.
Vitamin D.
Vitamin D₂.

SEQUESTRANTS

(For the purpose of this list, no attempt has been made to designate those sequestrants which may also function as chemical preservatives.)

Calcium acetate.
Calcium chloride.
Calcium citrate.
Calcium disacetate.
Calcium gluconate.
Calcium hexametaphosphate.
Calcium phytate.

Citric acid.
Dipotassium phosphate.
Disodium phosphate.
Monocalcium acid phosphate.
Monoisopropyl citrate.
Potassium citrate.
Sodium acid phosphate.
Sodium citrate.
Sodium diacetate.
Sodium gluconate.
Sodium hexametaphosphate.
Sodium metaphosphate.

Sodium phosphate (mono-, di-, tribasic).
Sodium potassium tartrate.
Sodium pyrophosphate.
Sodium tartrate.
Sodium tetrapyrophosphate.
Sodium tripolyphosphate.
Tartaric acid.

STABILIZERS

Agar-agar.
Carob bean gum (locust bean gum).
Carrageenin.
Guar gum.

Product	Tolerance	Specific uses or restrictions
ANTICAKING AGENTS		
Aluminum calcium silicate.....	2 percent.....	In table salt.
Calcium silicate.....	5 percent.....	In baking powder.
Calcium silicate.....	2 percent.....	In table salt.
Magnesium silicate.....do.....	Do.
Tricalcium silicate.....do.....	Do.
CHEMICAL PRESERVATIVES		
Benzoic acid.....	0.1 percent.....	
Butylated hydroxy-nisole.....	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content, of food.	
Butylated hydroxytoluene.....do.....	In cheese wraps.
Caprylic acid.....		
Dilauryl thiodipropionate.....	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
Gum gualac.....	0.1 percent (equivalent antioxidant activity 0.01 percent).	In edible fats or oils.
Nordihydroguaiaretic acid.....	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
Potassium bisulfite.....		Not in meats or in food recognizable as a source of vitamin B ₁ .
Potassium metabisulfite.....		Do.
Propyl gallate.....	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
Sodium benzoate.....	0.1 percent.....	
Sodium bisulfite.....		Not in meats or in foods recognizable as a source of vitamin B ₁ .
Sodium metabisulfite.....		Do.
Sodium sulfite.....		Do.
Sulfur dioxide.....		Do.
Thiodipropionic acid.....	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
EMULSIFYING AGENTS		
Cholic acid.....	0.1 percent.....	Dried egg whites.
Dexoxycholic acid.....do.....	Do.
Glycocholic acid.....do.....	Do.
Ox bile extract.....do.....	Do.
Taurocholic acid (or its sodium salt).....do.....	Do.
MISCELLANEOUS		
Caffeine.....	0.02 percent.....	In cola type beverages.
Ethyl formate.....	0.0015 percent.....	As fumigant for cashew nuts.
Magnesium stearate.....		As migratory substance from packaging materials when used as a stabilizer.
Sorbitol.....	7.0 percent.....	In foods for special dietary use.
Triethyl citrate.....	0.25 percent.....	Egg whites.
NUTRIENTS		
Copper gluconate.....	0.005 percent.....	
Cuprous iodide.....	0.01 percent.....	In table salt as a source of dietary iodine.
Potassium iodide.....do.....	Do.
SEQUESTRANTS¹		
Isopropyl citrate.....	0.02 percent.....	In salt.
Sodium thiosulfate.....	0.1 percent.....	
Succinyl citrate.....	0.15 percent.....	

¹ For the purpose of this list no attempt has been made to designate those sequestrants which may also function as chemical preservatives.

Effective date. This order shall become effective 30 days from the date of its publication in the **FEDERAL REGISTER**. (Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies sec. 400, 72 Stat. 948; 21 U.S.C. 348)

Dated: November 13, 1959.

[SEAL] **GEO. P. LARRICK**
Commissioner of Food and Drugs.

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